the transfer was filed in the aforesaid court for the District of Connecticut and thereafter the court denied the motion, stating that, since the case had been removed and all papers transferred to the Southern District of New York, a proper motion should be addressed to the court for that district. A motion was then filed in the United States district court for the Southern District of New York for the retransfer of the case to the District of Connecticut, and at the conclusion of the argument thereon, which took place on May 8, 1942, the court handed down the following opinion in denial of the motion:

GODDARD, *District Judge:* "The United States Attorney for the Southern District of New York moves for an order transferring this proceeding back to the United States District Court of Connecticut. It is urged in support of this motion that the case had been transferred from the United States District Court for the Western District of Pennsylvania to the United States District Court of Connecticut, and that under the provisions of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. § 334 (a)) the Connecticut Court was without power to transfer the case a second time, or to transfer the case to a district where the claimant has his principal place of business.

"Claimant contends that the order transferring the case to this court had been consented to by the United States Attorney for the District of Connecticut, and, accordingly, such transfer was permissible under the statute. I agree with this contention. The statute specifically provides that a proceeding 'pending or instituted' shall on application of the claimant be removed to any district agreed upon by stipulation between the parties. The consent of the United States Attorney for the District of Connecticut was in effect a stipulation. Nowhere is it provided that by stipulation a proceeding may be transferred only once, and then only to a district where the claimant does not have his principal place of business.

"Motion denied. Settle order on notice."

The case came on for trial before the court on October 29 and 30, 1942. At the conclusion of the trial the court took the case under advisement and on November 19, 1942, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE

1091. Misbranding of Phen-O-Sal Tablets. U. S. v. Dr. Salsbury's Laboratories. Plea of nolo contendere. Fine, $300 and costs. (F. D. C. No. 7709. Sample Nos. 76746–E to 76748–E, incl.)

On November 23, 1943, the United States attorney for the Northern District of Iowa filed an information against Dr. Salsbury's Laboratories, a corporation, Charles City, Iowa, alleging shipment on or about March 30, 1942, from the State of Iowa into the State of Minnesota of quantities of the above-named product.

Analysis of samples of the article disclosed that the tablets contained sodium phenolsulfonate, calcium phenolsulfonate, zinc phenolsulfonate, boric acid, a sugar, and approximately 0.34 grain of copper arsenite per tablet.

The article was alleged to be misbranded in that the statements in a circular accompanying the article which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of intestinal diseases, such as diarrhea, fowl cholera, typhoid, coccidiosis, and enteritis, and respiratory diseases, such as pneumonia, bronchitis, mycosis, roup, and colds; and that it would be efficacious in keeping chickens healthy, were false and misleading since it would not be efficacious for those purposes.

On November 23, 1943, the defendant having entered a plea of nolo contendere, the court imposed a fine of $300 and costs.

1092. Misbranding of Dr. Salsbury's Rakos, Can-Pho-Sal, and Phen-O-Sal Tablets. U. S. v. 2 Jugs, 1 Bottle, and 6 Bottles of Rakos (and 2 other seizure actions against the other above-named products). Motion to dismiss filed by the claimant, denied by the court. Tried to a jury; verdict for the Government. Decrees of condemnation and destruction entered. Execution of judgment stayed and motion for new trial filed; motion denied and products ordered destroyed. (F. D. C. Nos. 7564 to 7566, incl. Sample Nos. 76921–E to 76923–E, incl., 76955–E to 76957–E, incl.)

On June 1, 1942, the United States attorney for the District of Minnesota filed libels against the following products at Worthington, Minn.: 2 1-gallon jugs, 1 1-quart bottle, and 6 1-pint bottles of Rakos; 42 1-pint and 38 ½-pint bottles of Can-Pho-Sal; and 123 cans, of various sizes, of Phen-O-Sal Tablets. Thereafter, amended libels were filed to cover additional quantities of the above-named products and to clarify the allegations and, on or about May 28, 1943, further amended

libels were filed to include more specific allegations concerning the accompaniment in interstate commerce of the products by certain printed matter.

It was alleged in the libels as amended that the articles had been shipped in interstate commerce, from Charles City, Iowa, by Dr. Salsbury's Laboratories, within the period from on or about January 16 to May 26, 1942, and that they were misbranded.

Examination of the Rakos showed that it consisted essentially of sulfuric acid, hydrochloric acid, tannic acid, and sugar and water. It was alleged to be misbranded in that certain statements in the booklets entitled "Dr. Salsbury's Poultry Health Messenger," "Step-Up Profits By Improving Turkey Health," "Better Care Brings Greater Profits Now," and "Broiler Health and Disease Manual," were false and misleading, since they represented and suggested that the article was effective in the treatment of blackhead and coccidiosis in poultry, whereas it was not so effective.

Examination of the Can-Pho-Sal showed that it consisted essentially of creosote, camphor, pine oil, eucalyptus oil, soap, and water, with a small proportion of a potassium compound. It was alleged to be misbranded in that certain statements in the booklets were false and misleading since they represented and suggested that the article was effective in the treatment of pneumonia, bowel trouble, bronchitis, colds, and respiratory infections of poultry and farm animals, whereas it was not so effective.

Examination of the Phen-O-Sal Tablets showed that it consisted essentially of sodium phenolsulfonate, 76 percent; calcium phenolsulfonate, 3 percent; zinc phenolsulfonate, 4 percent; copper arsenite, 2.6 percent; boric acid, 12.4 percent; and a sugar. It was alleged to be misbranded in that certain statements in the booklets and in a leaflet entitled "Dr. Salsbury's Phen-O-Sal Tablets", accompanying the article, were false and misleading, since they represented and suggested that the article was effective in the treatment of bowel trouble, paratyphoid, coccidiosis, pneumonia, and diseases of the digestive tract of poultry, whereas the article was not so effective.

The amended libels further alleged that the booklets and the leaflet accompanied the articles when they were introduced into and while they were in interstate commerce in the following manner: That a number of copies of the booklets and the leaflet was received by the consignee at Worthington, Minn., from Dr. Salsbury's Laboratories, Charles City, Iowa, on or about January 14, and April 9 and 29, 1942; that certain of the booklets and the leaflet were thereafter prominently displayed in the consignee's establishment, together with and in association with and in close proximity to the articles; that the booklets, or some of them, were distributed to purchasers of the articles; and that the shipments of the articles and the delivery and receipt of each of the booklets and the leaflet constituted transactions in interstate commerce between Dr. Salsbury's Laboratories and the consignee.

Dr. Salsbury's Laboratories, a corporation, appeared as claimant for the articles and, on or about June 8, 1943, filed answers to the amended libels denying that the articles were misbranded; that the aforesaid booklets or leaflet accompanied the articles while they were in interstate commerce; or that they ever formed a part of the labeling of the articles. The cases came on for trial on June 8, 1943, at which time a motion was granted for their consolidation and, by unanimous consent of the court and counsel, an order was entered for the continuance of the matter. Thereafter a stipulation of facts was filed by the parties, after which a motion to dismiss the libels for lack of jurisdiction over the subject matter was submitted by the claimant. On September 13, 1943, an order was made denying that motion and on September 14, 1943, the case came on for trial before a jury. The trial was concluded on September 28, 1943, with the jury returning verdicts for the Government. On October 8, 1943, judgments of condemnation were entered against the above-named products and it was ordered that they be destroyed on or before November 9, 1943. On October 15, 1943, execution of the judgments was stayed to permit consideration of a motion which had been filed by the claimant for a new trial, and on October 30, 1943, oral argument on this motion was held, after which the matter was taken under advisement by the court for consideration of the arguments and briefs of counsel. On January 31, 1944, an order was entered in denial of the motion, accompanied by the following memorandum opinion of the court:

JOYCE, *District Judge:* "These proceedings arose as a result of libels of information filed by the United States on June 1, 1942, against certain quantities of

three articles of drug labeled in part 'Dr. Salsbury's Rakos', 'Dr. Salsbury's Phen-O-Sal', and 'Dr. Salsbury's Can-Pho-Sal', charging that these articles were misbranded in violation of the Federal Food, Drug and Cosmetic Act (21 U. S. C. section 301, et seq) and subject to seizure and condemnation. A monition was issued and the United States Marshal pursuant thereto attached the articles in the possession of Boote's Hatcheries and Packing Company, Worthington, Minnesota, hereinafter called 'the Hatcheries', where they had been shipped on various dates after January 1, 1942, by Dr. Salsbury's Laboratories, Charles City, Iowa, hereinafter called 'the Laboratories'. Thereafter the Laboratories intervened as claimant. As a result of preliminary proceedings, amended libels were filed by the United States. Each of the amended libels charged that the three articles were misbranded in violation of Section 502 (a) as a result of the association between the articles and five printed booklets. * * * These booklets, which are alleged to contain false and misleading representations concerning the effectiveness of the three articles in the treatment of specified diseases of poultry, were delivered to the Hatcheries by a sales representative of the Laboratories, and are alleged to have accompanied the articles in interstate commerce so as to constitute 'labeling' as defined in Section 201 (m) (2) of the Act. Each of the libels has attached as exhibits such portions of these booklets as the government alleged were false and misleading. Answers filed by the claimant denied that the booklets constituted 'labeling', denied that they contained false and misleading representations as to their effectiveness, and alleged that the three articles were not subject to seizure and condemnation under Section 304 (a) of the Act.

"In order that the court might pass upon the questions of whether the booklets are 'labeling' and whether the drugs are subject to seizure and condemnation, the parties stipulated the relevant facts. Claimant then moved to dismiss the libels upon the ground that the stipulation established that the articles of drug were not misbranded 'when introduced into or while in interstate commerce' as required by Section 304 (a), and, therefore, this court had no jurisdiction over the subject matter of these proceedings. On September 13, 1943, an order was made denying this motion.

"The three cases were consolidated for trial before a jury, and verdicts in favor of the United States were returned. The jury specially found that the three articles were misbranded. Appropriate decrees of condemnation and orders for destruction were submitted and approved. Claimant has now moved for new trials in each of the three cases and has assigned forty-five grounds of error.

"It is proper that consideration first be given to those specifications of error which attack the propriety of the order denying the motion to dismiss the proceedings for want of jurisdiction over the subject matter. Although the stipulation specifically applies to Civil 125, involving the product Rakos, the parties have agreed that it is also typical of and applicable to Civil 126 and 127, involving the products Phen-O-Sal and Can-Pho-Sal.

"From the stipulation it appears that the Laboratories is an Iowa corporation which distributes throughout the United States a line of poultry remedies designed for the prevention and treatment of diseases of poultry. Main offices are located at Charles City, Iowa, with branches at Columbus, Ohio, Forth Worth, Texas, and Kansas City, Missouri. Employing over 300 persons, the firm had sales in 1941 exceeding one million dollars. Distribution of its remedies is through hatcheries, drug stores, and feed and poultry houses, serviced by salesmen making regular calls.

"One such salesman is Mr. A. F. Achilles, a resident of St. Paul, whose sales territory includes Worthington, Minnesota, where the Hatcheries are located. Since his employment on January 1, 1937, Achilles has made monthly calls on dealers in his territory in the solicitation of orders and rendering poultry services. Several times yearly, printed matter is shipped to Mr. Achilles by the Laboratories for distribution to his customers. In calling upon dealers, Achilles furnished them, 'according to their needs and requirements and out of a supply carried in his car,' with the type of booklets here involved. 'Generally, Mr. Achilles, as part of his duties, on each of his regular calls on dealers, would determine whether sufficient quantities of the said booklets were on hand, and where the supply was low, it would be replenished out of supplies carried by him. Occasionally, a dealer, in order to maintain an adequate supply, would inform Mr. Achilles of his need for the said booklets without waiting for Mr. Achilles to check the quantity on hand.' Where dealers desired replenishment of their stock of booklets prior to Achilles' monthly visit, request would be made upon

the Laboratories, 'sometimes in connection with an order for merchandise,' and a supply would either be delivered by Achilles or sent in small quantities from Charles City, Iowa. 'During the spring and fall of each year as desired, a dealer would be provided by Mr. Achilles with window, counter, wall, and floor display cards and posters.'

"It further appears from the stipulation that the quantities of the product Rakos here involved were shipped in interstate commerce from Charles City, Iowa, via railroad, on January 16 and April 11, 1942, and via truck express, on May 4, 1942, to the Hatcheries at Worthington, Minnesota. Prior to these times, the booklets here involved had been shipped and cause to be shipped in interstate commerce by the Laboratories to Achilles at St. Paul, Minnesota. These were delivered by Achilles to the Hatcheries on January 14, 1942, and April 29, 1942, 'where they were prominently displayed together with, in immediate proximity to and in association with various articles of drugs manufactured and sold by Dr. Salsbury's Laboratories including specifically the articles of drug labeled in part 'Dr. Salsbury's Rakos' (including that quantity seized herein), 'Dr. Salsbury's Phen-O-Sal,' and 'Dr. Salsbury's Can-Pho-Sal', and were available for reading and accessible for distribution with the sale, actual or potential, of these articles of drugs. The posters and display cards of the type herewith submitted as Exhibits A through E, which had been delivered by Mr. Achilles prior to the dates specified herein, were similarly displayed.'

"It is also stated that in addition to being displayed and available with the drugs, the booklets 'are distributed by dealers . . . in over the counter transactions with purchases of one or more of the articles of drugs manufactured and sold by Dr. Salsbury's Laboratories including the articles of drug labeled in part, 'Dr. Salsbury's Rakos', 'Dr. Salsbury's Phen-O-Sal', and 'Dr. Salsbury's Can-Pho-Sal'. Also, a store patron may freely avail himself of one or more of the said booklets even though making no purchase.' It is also agreed that the principal distribution of Government's Exhibit 5, several million annually, is by direct mailing to farmers throughout the United States at the request of dealers. These are mailed from Mount Morris, Illinois, where they are printed.

"The following provisions of the Act are pertinent to claimant's contention. Section 502 (a), defines misbranding as follows: 'A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.' 'Labeling' is defined by section 201 (m) (2) to mean 'all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' So far as applicable, Section 304 (a), provides that 'Any article of . . . drug . . . that is . . . misbranded when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . .'

"The specific contention made by claimant is that the stipulation establishes that while the quantities of Rakos here involved were shipped on January 16, April 11, and May 4, 1942, the booklets had been shipped to Achilles prior thereto, and were delivered to the Hatcheries on January 14, and April 29, 1942. Therefore, there is said to be a complete lack of identity as to times of shipment, times of arrival and routes travelled between the drugs and the booklets. Accordingly, it is argued, the drugs were not misbranded 'when introduced into or while in interstate commerce' as required by Section 304 (a).

"In passing upon this contention, of paramount importance is the fact that the Federal Food, Drug & Cosmetic Act is an enactment under the Commerce Clause. Accordingly, in construing its provisions, consideration should be given to the purposes of the Act, its history, the specific terminology used therein and the enforcement procedures adopted. *Kirschbaum* v. *Walling*, 316 U. S. 517, 520. The history behind the present Act dates from 1906 when the Food and Drugs Act was adopted. 21 U. S. C., Sec. 1, et seq. One of the most important enactments under the Commerce Clause, its purposes of protecting the public health and pocketbook against adulterated and misbranded foods and drugs, have led courts to declare with unanimity that food and drug legislation should be given a liberal construction in order to accomplish its remedial purposes. *United States* v. *95 Barrels of Vinegar*, 265 U. S. 438; *United States* v. *Antikamnia Chemical Co.*, 231 U. S. 654, 655; *United States* v. *Schider*, 246 U. S. 519, 522; *Wm. M. Galt Co.* v. *United States*, (1913) 39 App. D. C. 470; *United States* v. *Research Commercial Creamery Co.*, (D. C. Wash. 1942) 43 F. Supp. 714, 715.

"Stating the basis for the enactment of the 1906 Act, the Court in *Hipolite Egg Co.* v. *United States*, 220 U. S. 45, 57, said: 'The statute rests, of course, upon the power of Congress to regulate interstate commerce; and, defining that power, we have said that no trade can be carried on between the states to which it does not extend, and have further said that it is complete in itself, subject to no limitations except those found in the Constitution.' That Congress was regulating what it regarded as illicit articles of commerce was made equally clear: 'We are dealing, it must be remembered, with illicit articles—articles which the law seeks to keep out of commerce because they are debased by adulteration, and which punishes them (if we may so express ourselves) and the shipper of them.' 220 U. S. at p. 57. In the case of adulterated articles, this illicit quality was supplied by the presence of a deleterious substance in the article (*Hipolite Egg Co.* v. *United States*, supra) and in the case of misbranding, it was supplied by the presence of a false label on the article. *McDermott* v. *Wisconsin*, 228 U. S. 115, 131–133. 'The object of the statute is to prevent the misuse of the facilities of interstate commerce in conveying to and placing before the consumer misbranded and adulterated articles of medicine or food.' 228 U. S. p. 131. The remedy of seizure and condemnation was said to be an appropriate means for preventing the transportation of such articles. *Hipolite Egg Co.* v. *United States*, 220 U. S. pp. 57–58.

"Inasmuch as Congress was dealing with what it regarded as illicit articles of commerce, it is not surprising that under the 1906 Act, the concept of misbranding was limited to the label or brand appearing upon the article or package. Accordingly, under Section 8 of the 1906 Act, an article was misbranded if 'the *package* or *label* . . . shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular.' (Emphasis supplied.) Any article so labeled was illicit in commerce. 'The label is the means of vindication or the basis of punishment in determining the character of the interstate shipment dealt with by Congress'. *McDermott* v. *Wisconsin*, 228 U. S. p. 133.

"It soon became apparent, however, that this concept of misbranding was too narrow. Thus a manufacturer could make false claims on a circular enclosed in the package containing the article without misbranding it under the phraseology of Section 8. *United States* v. *American Druggists' Syndicate* (C. C. N. Y. 1911), 186 Fed. 387; *United States* v. *Newton Tea & Spice Co.* (D. C. Ohio 1920), 275 Fed. 394. Congress in 1912 endeavored to correct this deficiency by passing the Sherley Amendment which defined as misbranded any article whose 'package or label shall *bear* or *contain* any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.' (Emphasis supplied), 21 U. S. C., Sec. 10 Third). The attack upon the constitutionality of this amendment was considered in *Seven Cases* v. *United States*, 239 U. S. 510. The Supreme Court decided that circulars bearing false and fraudulent therapeutic claims enclosed within the package containing the article would now misbrand it. Just as the label, under the 1906 Act, conferred upon the article its illicit character in commerce, so now the circular under the 1912 amendment provided this status. 'The false and fraudulent statement . . . in the package . . . gives to the article its character in interstate commerce.' 239 U. S. p. 517.

"So prior to 1938, the law protected the public only where false claims were made on the label or package or in a circular within the package. Accordingly, to avoid the jurisdiction of the Food and Drug Administration, a patent medicine manufacturer needed only to separate physically the printed matter bearing the false claims from the article itself. This and other deficiencies in the old Act resulted in its complete overhauling by Congress and culminated in the enactment in 1930 of the present Act. The avowed objective of the new Act was to strengthen the protection afforded the public by eliminating the loopholes and expanding consumer protection. Cong. Rec. 73rd Cong. 2nd session, Vol. 78, Part 5, pp. 4567–4573. Many new provisions were added and old ones enlarged. The concept of misbranding was expanded to include any drug whose 'labeling' is false or misleading. 'Labeling' comprehends labels, container wrappers, and all written, printed and graphic matter which accompanies any article of food or drug. Enforcement procedures were expanded by the inclusion of new prohibited acts and injunctive relief. (See Section 301, 303). The seizure and condemnation provisions were modified to eliminate obstacles to effectiveness and their availability was enlarged. (Compare Section 10, 1906 Act, with Section 304 (a), 1938 Act.)

"It is perfectly clear that to resolve the present controversy it is necessary to consider the interrelation of Sections 201 (m) (2) defining labeling, 502 (a)

defining misbranding, and 304 (a) providing for seizure and condemnation. Unless an article of drug is misbranded when it enters or while in interstate commerce, seizure is unavailable. There is no misbranding unless its labeling is false or misleading. Printed matter is labeling and will misbrand if it appears on the article, in the package or accompanies the article and is false or misleading in any particular.

"Realizing that Congress was attempting to expand the protection given consumers in redefining the concept of misbranding, it is evident that the word 'accompany' should be given an interpretation which accords with the Congressional purpose. There is evidence in the legislative history of the labeling section indicating that broad coverage was intended. Thus in addressing the Senate committee in regard to this section, W. G. Campbell, Commissioner of the Food and Drug Administration, stated: 'The term 'labeling' is defined so as to include not only the label but all circulars and material and placards for display purposes and the like that may in any form whatever accompany the article of food, drug or cosmetic . . . .' United States Senate Report 1944, 73rd Cong. 2nd Session, p. 16. There is nothing elsewhere in the history which in any way indicated that anything less than that was intended.

"The narrow question here is the extent to which printed matter must 'accompany' articles of drug at the time of introduction into or while in interstate commerce in order that such articles can be said to be 'misbranded' within the meaning of Section 304 (a). In answer to this question, the government states that the old physical contiguity test of misbranding operative under the old law has been discarded and the present act should be given the broadest possible interpretation in accomplishing the consumer protection intended by Congress. Claimant states that it does not believe that physical annexation between the drug and printed matter is always necessary, but insists that because there are differences in times of shipment, times of delivery and routes travelled, the drugs here seized could not possibly have been 'misbranded' at any time in their interstate journey.

"The provision in Section 304 (a) that an article to be subject to seizure must have been 'misbranded' during its interstate journey is the counterpart in the present Act of the theory and terminology of Section 10 of the old Act (21 U. S. C. Sec. 14). Thereunder, seizure was available as to any 'article of . . . drug . . . that is . . . misbranded . . . and is being transported from one State . . . to another . . .' Since the concept of misbranding was then limited to printed matter physically contiguous with the article, necessarily there was an actual physical misbranding throughout the interstate journey. However, as we have seen, the concept of misbranding has now been extended by Congress beyond this restricted notion of physical contiguity. Since Congress should not be thought to have expanded the substance without expanding the remedy, in asking whether an article is 'misbranded' in commerce as required by Section 304 (a), we must necessarily apply the enlarged concept which the law has now created. The full scope of the present concept of misbranding must be applied in the interpretation of Section 304 (a). As we have seen, Congress was dealing in this legislation with articles which were regarded as illicit. Accordingly, just as it was the label in 1906 and the circular in 1912 which conferred upon an article its misbranded status in commerce, so now under the present Act, printed matter which can be said to have accompanied an article confers its misbranded status in commerce.

"Aside from the theory of the food and drug legislation, it is manifest that misbranding has true significance only in terms of the consumer. It matters little whether a farmer goes to Boote's Hatcheries and sees a large display card proclaiming the benefits of Rakos in the treatment of coccidiosis, or finds the same matter actually upon the carton or label of the product. If such representations are false, he is as much defrauded irrespective of the location of the printed statement. Nor does it matter to the farmer whether the booklets were physically side by side with bottles of Rakos during the interstate journey, or were delivered by a salesman. When the farmer enters a dealer's store, he finds the Rakos and the booklets together in one indivisible merchandising unit. Nothing on the bottle of Rakos, or on or in the carton in which it is sold tells the farmer that Rakos shall be used in the treatment of coccidiosis. The only statements to that effect are found in booklets displayed and distributed with Rakos and upon placards and wall posters prominently arranged in the store. The fact that the farmer has suffered an out-of-pocket loss by relying upon these representations should not be obscured by any

subtle inquiries concerning whether the printed representations rode with the drugs on the same train, at the same time or over the same route.

"In support of its claim that seizure and condemnation are available here, the Government has made three contentions. First, it claims that if printed matter at any time after an interstate shipment of drugs comes into a relationship which complies with the requirements of 'labeling', the misbranding which then occurs is retroactively effective from the moment the drugs entered the channels of commerce. Although the use by the drugs of the facilities of commerce seemingly is proper, yet the end result was the misbranding which Congress sought to avoid, and this wrong was a wrong ab initio. Second, the Government contends that the stipulation establishes that the drugs were 'misbranded' in commerce because the facts show that the booklets did actually accompany the drugs in commerce. Third, the Government contends that the booklets and drugs were part of one interstate transaction, and that 'commerce among the states is not a technical legal conception, but a practical one, drawn from the course of business.' *Swift & Co.* v. *United States*, 196 U. S. 375, 398. Since I concur in the correctness of the second contention, it is unnecessary to consider either of the other arguments.

"In essence the question is: Must there be physical accompaniment throughout the entire interstate movement of the drugs in order for seizure and condemnation to be available? The question is answered in the negative. So to hold would be to resurrect the physical proximity theory of misbranding. May not an article be 'misbranded' in commerce within the meaning of Section 304 (a) by printed matter which, though not physically contiguous thereto, nevertheless actually did 'accompany' the article for all practical purposes and in all significant aspects? This question is answered in the affirmative.

"The answer to these questions was first made in *United States* v. *Research Laboratories*, (C. C. A. 9, 1942) 126 F. (2d) 42, where the libel, which the lower court dismissed, alleged that the circulars accompanied the articles in commerce by having the same origin and in simultaneously arriving with the articles at destination where they were placed in the same room in the consignee's warehouse. In reversing the lower court, the court said: 'The libel does not state, nor is it material, whether the packages and the circulars did or did not travel in the same crate, carton or other container or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simultaneously. *Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey.*' (Emphasis supplied). The principle of that case in rejecting the concept of physical contiguity as a test for misbranding under Section 304 (a), in my opinion is sound. Once this principle is comprehended, it is simply a question of determining in a given case whether the relationship between the article and the printed matter is sufficiently proximate to fulfill the requirements of accompaniment.

"The word 'accompany' as used in Section 201 (m) (2) was said in *United States* v. *Lee*, (C. C. A. 7, 1942) 131 F. (2d) 464, 466, to mean: 'The word 'accompany' is not defined in the Act, but we observe that among the meanings attributed to the word are 'to go along with,' 'to go with or attend as a companion or associate,' and 'to occur in association with, Webster's New International Dictionary, 2d Ed.' Naturally, meanings of accompany will vary in connection with subject matter 'Accompany' as used in this Act is used to describe a relationship between an article of drug and its labeling. Since there 'can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates' (*United States* v. *Lee*, at p. 466), the booklets here involved should be scrutinized from this viewpoint. In the sense just stated, if the booklets are not labeling, then the products Rakos, Phen-O-Sal and Can-Pho-Sal have none.

"The stipulation clearly shows that the printed matter and the drugs had a common origin. They had a common destination in that both were intended to come together in the stores of dealers in Achilles' territory. They were interlocking units of a distributional scheme the objective of which was ultimate association and distribution together. There was actual, physical association together in the stores of dealers and actual distribution together in connection with purchases by farmers. It is fair to conclude that these booklets were prepared, shipped and distributed to dealers with the ultimate expectation and intention on the part of the Laboratories that they would serve the purpose of labeling for the three articles of merchandise here involved. Without the book-

lets, the products themselves lacked labeling, at least in so far as informing purchasers of the purposes and uses of the remedies. The mere fact that the products were shipped at a different time, over a different route and were received at a different time from the booklets should not be permitted to confuse or obscure the substance of the matter. The instant that the product Rakos entered the channels of commerce enroute to the Hatcheries, it was to all intents and purposes as much travelling in accompaniment of the representations contained in the booklets as if those booklets were actually enclosed in the same shipping container. It is unquestionable that both the drugs and the booklets used the facilities of interstate commerce to accomplish a defrauding of the public. For this transgression, the products are subject to seizure and condemnation.

"Were not the factors just stated to be given primary consideration, there would be a multiplication of refinements. Starting with the case of a circular in the package or in the shipping carton containing the drug, there would be a question as to circulars in a different car on the same train, or a different train, at a different time, over a different route, or by a different type of carrier. The physical aspects of the transportation are not important. What is vital here are such factors as interdependence of the drug and the booklets, common origin, common destination, display, distribution and use together. These determine whether there has been that degree of accompaniment which provides the necessary 'misbranded' status under Section 304 (a). The mere fortuitous circumstance of an absence of physical association between the booklets and drugs during the interstate journey of the drugs does not in my opinion control.

"Claimant insists, however, that there is no occasion for employing seizure and condemnation in this situation as the Government has a right to proceed by injunction under Section 301 (k).[1] Claimant states that this section authorizes the Government to enjoin the Laboratories from causing an association between the printed matter and the drugs at the retailer's place of business. *United States* v. *Lee*, supra. The Government, however, does not concede that this section is necessarily available here and suggests several arguments which claimant might have made as to the non-applicability of Section 301 (k) had the Government attempted to use it.

"This Court does not in this proceeding propose to mark out the limits of Section 301 (k). Seemingly, however, it was enacted by Congress under its authority to regulate activities affecting interstate commerce. See *Labor Board* v. *Jones & Laughlin*, 301 U. S. 1. In referring to alteration, mutilation, destruction, obliteration or removal of labels this section at least suggests the possibility that what it contemplates is a lawful use by a drug of the facilities of interstate commerce followed by some activity which causes it to be misbranded. In the instant case, drugs and booklets were flowing through commerce in a relationship which has been found to make illegal the use by the drugs of the facilities of commerce. In any event, in absence of further clarification, it cannot be said that the applicability of Section 301 (k) to the facts set forth in the stipulation is so clear that doubts should be entertained as to the applicabilty of Section 304 (a).

"The ground of error most vigorously asserted by claimant in its motion goes to the failure of the court to grant certain requested instructions. Requests 3 and 4 were as follows:

" 'The law under which this proceeding is instituted does not contemplate that statements with reference to the curative or therapeutic value of the drugs shall be deemed false or misleading with respect to matters as to which there is an honest difference of opinions between schools and practitioners.

" 'In the treatment of diseases of animals honest differences of opinion may arise between school and practitioners as to the therapeutic or curative value of drugs. Statements with reference to the curative value of drugs or helpfulness in assisting in bringing about a cure are not to be deemed false and misleading merely because differences of opinion exists between different groups of Veterinarys, or different groups skilled in this particular line of endeavor as to the curative value.'

[1] The full text of Sec. 301 (k) is as follows: "The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

"Failure to grant these requests is said to have constituted unconstitutional application of Section 502 (a), for the reason that it permitted the jury to find claims of effectiveness to be false and misleading upon the basis of differences of expert opinion. Failure to charge as requested is said to have permitted the jury to weigh differences of expert opinion and to decide whether the claims of effectiveness made by claimant were false or misleading depending upon whether it followed the experts for the Government or those for claimant. This, it is said, introduced such uncertainty into Section 502 (a) as would make it void for uncertainty. Cases cited in support thereof are *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94; *United States* v. *Johnson*, 221 U. S. 488; *Seven Cases* v. *United States*, 239 U. S. 510, and cases holding that a statute must define an offense with reasonable certainty in order that a person may know what is prohibited. *United States* v. *Cohen Grocery Co.*, 255 U. S. 81; *Connally* v. *General Const. Co.*, 269 U. S. 385.

"The law under which these proceedings were instituted provides that a drug is misbranded if its labeling is false or misleading in any particular. There is nothing in this standard which is vague or indefinite. It prescribes a rule of conduct by which persons can measure their acts. In and of itself there is and can be no contention that the provisions of Section 502 (a) are void for indefiniteness and uncertainty. *United States* v. *Cohen Grocery Co.*, supra; *Connally* v. *General Const. Co.*, supra; *Coplin* v. *U. S.* (C. C. A. 9, 1937) 88 F. (2) 652, 657.

"Claimant, however, supports its contention that the standard is uncertain and indefinite by adding another element, the difference of opinion between the experts appearing for the Government and those appearing for claimant. It is said that the question of 'whether or not these remedies are of value in the treatment of poultry diseases involves a question of opinion and not a strict question of fact'. Therefore, it is concluded, refusal to charge the jury as requested in 3 and 4 placed an unconstitutional interpretation upon Sec. 502 (a) by allowing the jury to find the claims of effectiveness false or misleading by deciding between two groups expressing different opinions about the effectiveness of these remedies.

"Implicity, the argument for claimant proceeds upon the assumption that it would be beyond the power of Congress to permit a claim of effectiveness to be found false by a jury where medical or veterinary opinion is divided on the matter. Whatever the merit of this assumption, it is clear that Congress has not attempted to do this in Section 502 (a), nor did it do so in prior legislation. What Congress had done is to permit a claim of effectiveness to be found false or misleading where the question of effectiveness is demonstrable as a fact. I do not think that I have permitted more in these proceedings.

"The law is regarded to the effect of a difference of medical opinion upon a proceeding in which a claim of effectiveness is sought to be proved false stems from *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94. In that case, the Postmaster General upon the basis of evidence satisfactory to him, issued a fraud order upon the ground that the Magnetic Healing School was using the mails to obtain money by means of false and fraudulent pretenses. An injunction was sought to restrain the Postmaster from carrying out the terms of the fraud order. A demurrer to the bill was sustained in the lower court and reversed on appeal. Laying constitutional consideration to one side, the Supreme Court held that the School's claims of effectiveness for its method of treatment of diseases, as to which there was a difference of medical opinion, could not be condemned as false for the reason that, being based upon differences of opinion, there was no standard of fact or truth by which to measure the falsity of the claims. The court stated that efficacy of treatment was a matter of opinion entirely and not a matter of absolute fact capable of proof as a fact. Under the statute, the Postmaster General was said to have no authority to decide between the conflicting opinions. The Court held that where variant opinions appear as to claims of effectiveness, such a statute does not apply as a matter of law.

"Later cases made the McAnnulty rule applicable to food and drug legislation under which statements constituted misbranding where false or misleading in any particular (1906 Act), or false and fraudulent (1912 Amendment), as applied to curative claims. *United States* v. *Johnson*, 221 U. S. 488; *Seven Cases* v *United States*, 239 U. S. 510. Although the majority of the court in the Johnson case believed that Section 8 of the 1906 Act in declaring as misbranded statements which were false or misleading applied only to statements of strength,

identity, quality and purity and did not apply to claims of curative value, and intimated that Congress was unlikely to distort its constitutional power to establish criteria in regions where opinion is wide apart, yet it is significant that the deciison does not rest upon a constitutional basis. It was simply decided that Section 8 was not intended to apply to expressions of curative value. Following this decision, Congress amended the 1906 Act expressly to provide that statements of curative value would constitute misbranding if 'false and fraudulent'. When the constitutionality of this amendment was attacked upon the same ground as claimant advances here, a unanimous court in *Seven Cases* v. *United States* held that the amendment was intended to apply not to expressions of opinion but only to expressions of effectiveness which were plainly contrary to fact.

"Although the court in the McAnnulty case had said that assertions of effectiveness were always matters of opinion because 'There is no exact standard of absolute truth by which to prove the assertion false and a fraud . . . [since] . . . the claim . . . cannot be the subject of proof as of an ordinary fact,' 187 U. S. 104, the court now states that there is a category of assertions which fall outside the field of opinion and into the field of fact. 'Congress deliberately excluded the field where there are honest differences of opinion between schools and practitioners . . Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion, but constitute absolute falsehoods.' *Seven Cases* v. *United States*, 239 U. S. p. 517. In view of the fact that Justice Hughes, who spoke for a unanimous court in *Seven Cases* v. *United States*, dissented from the majority opinion in the Johnson case as to the scope of Section 8 of the 1906 Act, the language which he used in his dissent is of significance upon this question. He stated, 'It is, of course, true, that when Congress used the words 'false or misleading statement,' it referred to a well defined category in the law, and must be taken to have intended statements of *fact*, and not mere expressions of opinion . . . But, granting the widest domain of opinion, and allowing the broadest range to the conflict of medical views, there still remains a field in which statements as to curative properties are downright falsehoods and in no sense expressions of judgment. This field I believe this statute covers.' 21 U. S. p. 504. In using this language, Justice Hughes was referring to terminology in the 1906 Act which is in all respects identical with that contained in Section 502 (a).

"Plainly, therefore, the subject of regulation in the 1938 Act, as in its predecessors, is matter of fact, not matter of opinion. See House Committee Report No. 2139, 75th Congress, 3d Session. Except as affected by Section 201 (n) and the regulations issued thereunder, it is clear that food and drug legislation was intended to apply only to false or misleading expressions of fact. It seems manifest that the question of whether a remedy is effective is always a question of fact. A remedy cannot be both effective and ineffective under identical circumstances. The susceptibility of effectiveness to proof as a fact necessarily determines whether assertions can be adjudged false or misleading within the meaning of Section 502 (a). Necessarily, therefore, whether in a given case the question of effectiveness is one of opinion or fact depends entirely upon the evidence which is introduced.

"Under the law as it now exists, before a court is warranted in submitting the false or misleading qualities of an assertion of effectiveness to a jury to decide, it must be satisfied that something more is involved than mere difference of opinion between schools or practitioners. As stated by Justice Hughes in his dissent in the Johnson case, 'I entirely agree that in any case brought under the act for misbranding—by a false or misleading statement as to curative properties of an article—it would be the duty of the court to direct an acquittal when it appeared that the statement concerned a matter of opinion. Conviction would stand only where it had been shown that, apart from any question of opinion, the so-called remedy was absolutely worthless, and hence the label demonstrably false,' 221 U. S. 507. If the evidence is such that it appears that the question of effectiveness has not transcended the realm of opinion into the realm of demonstrable fact, the court must hold as a matter of law that assertions of effectiveness are not false and refuse to submit the question to the jury. *American School of Magnetic Healing* v. *McAnnulty*, supra; see *L. B. Silver* v. *Federal Trade Commission* (C. C. A. 6, 1923), 289 Fed. 985; cf. *Bruce* v. *United States*, (C. C. A. 9, 1912) 202 Fed. 98. But where the evidence indicates that there is a standard of demonstrable truth and fact by which the jury can measure the claims of effectiveness, the court should then submit the question to the jury under appropriate instructions. What the evidence shows in a given case is a question of law for the court to decide.

"In light of these considerations, it appears that the claims of unconstitutionality made by claimant as to the interpretation given to Section 502 (a) in the charge are not well taken. The only situation where claimant could possibly say that its claimed constitutional rights had been invaded would be where a court had permitted the jury to find a claim of effectiveness false on the basis of evidence which indicated only a contrariety of opinion. No possible question of constitutionality can arise in a case where the evidence upon which the question of effectiveness was decided by the jury has the necessary factual basis. Such factual proof was present at the time these cases were submitted to the jury.

"Scientific witnesses for the Government in this case made elaborate and comprehensive tests of claimant's remedies under conditions most favorable to the remedies. Practically all of the experts testifying for the Government had conducted significant experimentation either in the field or in the laboratory. In the experimentation, all factors were controlled and a complete identity of circumstances and environmnet for the experimental poultry was provided. The report of such tests showed conclusively that the remedies were absolutely worthless and without any benefit whatsoever. The infected, untreated experimental group showed the same rate of mortality and recovery as the infected, treated group. These tests were duplicated and corroborated away from the laboratory under so-called field conditions. These tests were recognized by outstanding men of science as constituting conclusive evidence by recognized scientific standards that the remedies were wholly ineffective.

"Facts established by recognized scientific investigation are deserving of high standing in respect to the falsity of claims of effectiveness. *Elliott Works* v. *Frisk*, (D. C. Iowa 1932) 58 F. (2d) 820, 824–825; cf. *United States* v. *Lesser*, (C. C. A. 2, 1933) 66 F. (2d) 612, 616. Moreover, it must be obvious that tremendous advancements in scientific knowledge and certainty have been made since the rule in the McAnnulty case was first announced. Questions which previously were subjects only of opinion have now been answered with certainty by the application of scientifically known facts. In the consideration of the McAnnulty rule, courts should give recognition to this advancement.

"None of the experimental data introduced by claimant in any way directly or completely opposed the conclusiveness of the experimentation conducted by Government experts, and the jury was entitled to find that it was lacking in significance. It is true that claimant produced veterinarians from its own organization and from other remedy companies who expressed the opinion that these remedies were effective. But it is unthinkable that this expression of opinion by these so-called experts could in any way operate to prevent these cases from being submitted to the jury or to require the court to instruct the jury to ignore all expressions of opinion on the part of both sides.

"But the requested instructions did not in any way raise these issues. The requests did not ask the court to instruct the jury to ignore all opinion testimony. As the summation by claimant's counsel indicated, claimant was perfectly willing that the jury should have the benefit of the opinions rendered by its experts that these remedies were effective. Accordingly, the jury was instructed that the issue of misbranding, i. e. the question of effectiveness, should be decided upon a consideration of all the testimony. Certainly where factual proof is present which indicates the worthlessness of the remedies in question, mere injection of an alleged difference of opinion on the part of persons whom the jury might find were either ignorant or charlatans, could not operate to prevent the jury from deciding the question of effectiveness. Under the evidence in this case, the jury was entirely warranted in finding that the contrary expressions of opinion by the witnesses appearing for claimant were in direct opposition to established scientific fact.

"The only possible question which claimant's requests raised was whether there was in the evidence any more than mere difference of opinion between groups of veterinarians. Since there was abundant factual evidence of ineffectiveness, the requests served no purpose and were therefore refused. Certainly there was no occasion for telling the jury about what the rule would have been had the evidence been different than it was.

"Failure to give other requested instructions is also assigned as error. These asked that the jury be told that the booklets did not represent that the remedies would cure, but merely indicated that the remedies would be helpful. Also, requests were made as to what degree of helpfulness a drug must have in order that it possess therapeutic or curative properties.

"The libels in this case charged that the representations contained in the booklets were false and misleading because they represented that the remedies were effective in the treatment of poultry diseases when they were not effective. Whether they were represented to be effective and whether they were effective were the issues in the case. The testimony for the Government, acquiesced in by three witnesses for claimant, was that before these remedies could be effective, a capacity to destroy or inhibit germs was necessary. Under this state of the evidence, it was unnecessary to tell the jury about what would be necessary for the remedies to be curative or therapeutic. Whether the statements appearing in the booklets represented the remedies to be effective was for the jury to say in light of the ordinary meaning of the language used. *Bradley* v. *United States*, (C. C. A. 5, 1920) 264 Fed. 79; *Hall* v. *United States*, (C. C. A. 5, 1920) 267 Fed. 795; *United States* v. *John J. Fulton Co.*, (C. C. A. 9, 1929) 33 F. (2d) 506.

"Claimant assigns as error the action of the court in permitting the experts for the Government to testify as to the ultimate issues in the case, citing *United States* v. *Spaulding*, 293 U. S. 498. All of the opinion evidence given by the Government's experts necessarily involved the use of their experience and training on matters of special knowledge not within the grasp of the untutored. Clearly, it would seem not improper for the court to permit them to express opinions upon the question of the effectiveness of claimant's remedies. *Dr. J. H. McLean Medicine Co.* v. *United States*, (C. C. A. 8, 1918) 253 Fed. 694; *Eleven Gross Packages* v. *United States*, (C. C. A. 3, 1916) 233 Fed. 71; *Kar-Ru Chemical Co.* v. *United States*, (C. C. A. 9, 1920) 264 Fed. 921; *United States* v. *Chichester Chemical Co.*, (App. D. C. 1924) 298 Fed. 829. All opinions given by the experts who testified for the Government were directly or indirectly expressed in relation to this question of effectiveness and did not invade the function of the jury. Moreover, in the examination of its experts, claimant was allowed similar latitude. In fact, in an effort to permit claimant to present to the jury everything which could possibly be of benefit in support of its claims of effectiveness, the court allowed very great latitude in the receipt of evidence, even to the point where opinion evidence from lay persons was received. Accordingly, if any error was committed, it was in claimant's favor and it is now in no position to complain.

"Other claims of error may be summarily dismissed. I see no impropriety in instructing the jury to ignore such portions of the closing argument of claimant's counsel as attempted to impugn the Government's motives in bringing this case at the present time. There was no evidence to justify this statement. See *London Guarantee & Accident Co.* v. *Woefle*, (C. C. A. 8, 1936) 83 F. (2d) 325, 338–344. The claimed impropriety in the argument of Government counsel, if it existed, was prompted by the improper argument of opposing counsel and was not open to censure. *Chicago & N. W. Ry. Co.* v. *Kelly*, (C. C. A. 8, 1934) 74 F. (2d) 31; *Union Electric Light & Power Co.* v. *Snyder Estate Co.*, (C. C. A. 8, 1933) 65 F. (2d) 297, 301–302.

"I feel that claimant's requests to permit the jury to examine all parts of the booklets in determining whether there were representations of effectiveness was properly denied. Much of this matter was wholly unrelated to the remedies involved and would have diverted the jury from the task at hand. Request No. 18, submitted by claimant, was granted and this in my opinion was all that it was entitled to.

"Throughout the trial, evidence as to efficacy of the remedies was offered by both sides without regard to whether it related to prevention or treatment of disease. It was, therefore, entirely proper to permit the Government to amend its pleadings to embrace both. Rule 15 (b) of the Federal Rules expressly sanctions this.

"Any error in the exclusion of Exhibit P was harmless. The materiality of and foundation for this exhibit were not clearly shown. But that aside, it was offered as impeachment evidence only. In view of the admission of Exhibit Q, its only effect would have been cumulative."

On June 27, 1944, judgments were entered ordering that the products be destroyed on or before July 31, 1944. The United States marshal destroyed them on July 8, 1944.

1093. Misbranding of Schilling's Mercutol. U. S. v. 124 Bottles of Schilling's Mercutol. Default decree of condemnation and destruction. (F. D. C. No. 9412. Sample No. 9828–F.)

On February 25, 1943, the United States attorney for Southern District of Mississippi filed a libel against 124 6-ounce bottles of Schilling's Mercutol at Jackson, Miss., alleging that the article had been shipped on or about October 5